REMARKS

Claims 1-3, 5, 6, 9-11, 19-21, 23, 24, 27-29 and 39 remain active in the application.

Claims 1, 3-10, 12-19, 21-28 and 30-39 are rejected under 35 U.S.C. §103(a) as being obvious over Hewitt et al, Lozada and Sharpe et al. in view of Battet al.

The present invention relates to methods for treating or preventing graft v. host disease of the mouth, which include specific steps adapted to treatment of this particular immune disease.

The examiner has withdrawn a previous rejection over Hewitt, Lozada and Sharpe and added the Batt et al. reference. Batte et al. discloses that azathioprene can be used as a supplemental immunosuppressive agent for treating organ transplant rejection in general and graft vs. host disease (col. 7, line 31). However, azathioprene is not the sole immunosurpressive agent. The present claims are limited to a very small group immunosuppressive compounds by virtue of the phrase "consisting of" in line 3 of amended claim 1.

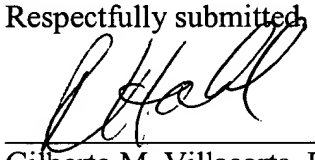
Hewitt et al. teaches the use of cyclosporine in ointment formulations, for site-specific immune suppression, optionally combined with hydrocortisone or other immunosuppressants. While graft v. host disease is mentioned (col. 1, line 13 – 18), it is in connection with the well-known effectiveness of cyclosporine for treating T-cell mediated immune processes, such as allograft rejection, graft-versus-host disease, and autoimmune disease when administered systemically. This information would not have suggested the effectiveness of an azathioprine swish, as claimed, for treatment of this specific kind of immune disorder.

Lozada discloses topical treatment of mucosal lesions with immunosuppressants. Lozada's method involves the use azathioprine to lower the effective dose of prednisone (synergy). This method is not topical , and while it is indicated for several kinds of mucosal diseases including chronic inflammatory mucocutaneous disease (CIMD), lichen planus (LP), and others), graft v. host disease, which involves mouth lesions caused by tissue transplants away from the mouth, is not mentioned.

Sharpe et al. teaches a topical method for treatment of mucosal lesions using N-acetyl cysteine as the main active ingredient, with azithioprine as a secondary compound for enhancing the effectiveness of N-acetyl cysteine. As in Lozada, the difficult problem of graft v. host disease is not discussed.

Nothing in Batt et al., Lozada or Sharpe et al. would have suggested to a person of ordinary skill in the art that is selecting liquid formulations of the claimed compounds would be particularly effective for treatment of graft v. host disease; thus, the present invention would not have been obvious within the meaning of 35 U.S.C. §103(a).

Respectfully submitted,



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